### UNITED STATES DISTRICT COURT DISTRICT OF SOUTH DAKOTA WESTERN DIVISION

FILED JAN 2 6 2017

REDACTED VERSION

CLERK CLERK

CR: 17 -50020

### **INDICTMENT**

UNITED STATES OF AMERICA,

Plaintiff,

ν.

ROBERT LARRY LYTLE (a.k.a. Larry Lytle);

IRINA KOSSOVSKAIA; and

FREDRETTA L. EASON,

Defendants.

CONSPIRACY 18 U.S.C. § 371

CRIMINAL CONTEMPT 18 U.S.C. § 401(3)

MAIL FRAUD 18 U.S.C. § 1341

WIRE FRAUD 18 U.S.C. § 1343

OBSTRUCTION OF AGENCY PROCEEDINGS 18 U.S.C. § 1505

AID AND ABET 18 U.S.C. § 2

FORFEITURE ALLEGATION 18 U.S.C. § 981; 28 U.S.C. § 2461

#### THE GRAND JURY CHARGES:

At all times material to this Indictment, unless otherwise alleged:

#### **BACKGROUND AND GENERAL ALLEGATIONS**

#### The Defendants

1. Defendant ROBERT LARRY LYTLE (a.k.a. Larry Lytle), a resident of South Dakota, owned, operated, and controlled a number of business entities based in Rapid City, South Dakota, that were involved in the designing, manufacturing, packing, labeling, holding, marketing, selling

and distributing of medical devices known as "QLasers," a collection of various apparatuses marketed as low level laser therapy devices for home use. At various times, these entities included the following:

- **2035** Inc.
- 2035 PMA
- 2035 PMA Trust
- **2035**, Inc.
- Dewot Limited Partnership
- Energy for Life Limited Partnership
- Go-Jo Limited Partnership
- Health and Wellness, Inc.
- Lasers, Inc.
- Low Level Lasers, Inc.

- Old Cap Trust
- Old Cap, Inc.
- Overshot Limited Partnership
- QLaser Healing Light Limited Partnership
- QLasers PMA
- Subtle Energy Limited Partnership
- Windor Limited Partnership
- Windy Knob Limited Partnership
- Wowapi, Inc
- 2. Defendant IRINA KOSSOVSKAIA, a resident of Canada, owned, operated, and controlled business entities that sold, marketed, and distributed QLaser devices in interstate commerce in active concert and participation with LYTLE as a QLaser distributor. At various times, these entities included:
  - HealthBoss
  - HealthBoss LLC
  - HealthBoss-Mediscen
  - Mediscen (Canada)

- Mediscen (Niagara) Inc.
- Mediscen (U.S.A.) Inc.
- Mediscen Health Centre
- Mediscen Niagara, Inc.
- 3. Defendant FREDRETTA L. EASON, cohabited with LYTLE in South Dakota, maintained partnership interests in several of the entities involved in the QLaser business, and acted in concert and participation with LYTLE to sell QLaser devices and distribute them in interstate commerce.

#### The QLaser Medical Device System

- 4. Beginning at least as early as about 2005, LYTLE marketed and distributed the QLaser devices to consumers throughout the United States by falsely claiming that the QLaser devices safely and effectively treated a panoply of medical conditions at home, including *e.g.*, cancer, heart attacks, paralysis, HIV/AIDS, and diabetes.
- 5. In addition to selling QLasers directly to consumers, LYTLE also sold QLasers to a network of distributors, including KOSSOVSKAIA, who then marketed and re-sold the devices to consumers, using support, tools, training, and resources provided by LYTLE.
- 6. LYTLE and KOSSOVSKAIA, along with other QLaser distributors, sold the devices alone and in combination packages mostly to elderly consumers for prices that ranged from approximately \$4,000 to \$13,000 or more.

#### The Prior Civil Enforcement Action

- 7. Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), the United States Food and Drug Administration ("FDA") was the federal agency charged with protecting the health of the American public by ensuring that medical devices that were marketed in the United States were safe and effective for their intended uses, and by preventing those that were unsafe or ineffective from finding their way into the hands of American consumers.
- 8. Under federal law, unless explicitly exempted by law or regulation, all medical devices were required to be evaluated by FDA for safety and effectiveness for each of the devices' intended use(s) before being distributed in interstate commerce.
- 9. Despite receiving numerous warnings from the FDA since 2002 that selling QLaser devices in the United States for uses that FDA had not cleared or approved was unlawful under

the FDCA, LYTLE and several of his distributors, including KOSSOVSKAIA, continued to distribute the QLaser devices in interstate commerce through about 2016.

- 10. On or about October 21, 2014, the United States filed a civil complaint in this Court against LYTLE and his businesses seeking to permanently enjoin him from violating the FDCA. Along with the complaint in that action, the government moved for the entry of a preliminary injunction to enjoin Lytle and those operating in concert and participation with him from further violating the FDCA. *See generally* Compl. for Inj., *United States v. 2035 INC. et al.*, No. 14-cv-5075-JLV (D.S.D. Oct. 21, 2014), ECF No. 1 & Mot. for Prelim. Inj., (Oct. 21, 2014), ECF No. 4.
- 11. On or about January 14, 2015, this Court issued an Order of Preliminary Injunction against LYTLE and his businesses. That Order prohibited LYTLE and all persons in active concert or participation with him who received notice of the injunction from, *inter alia*, "directly or indirectly manufacturing, designing, processing, packing, labeling, holding or distributing for sale or otherwise any article of device, including but not limited to [QLaser model numbers]." Prelim. Inj., 2035 INC. (Jan. 14, 2015), ECF No. 48. In addition, the Preliminary Injunction ordered LYTLE to permit FDA to inspect his operations, including his business records.
- 12. On or about October 6, 2015, this Court entered an Order of Permanent Injunction in the civil enforcement action. Perm. Inj., 2035 INC. (Oct. 6, 2015), ECF No. 138. That Order was amended with only grammatical and non-substantive revisions on or about October 13, 2015. Amend. Perm. Inj., 2035 INC. (Oct. 13, 2015), ECF No. 139 (hereinafter collectively referred to as the "Permanent Injunction"). As with the Preliminary Injunction that preceded it, the Permanent Injunction prohibited LYTLE and all persons acting in concert or participation with him from manufacturing, storing, and distributing QLaser devices.

13. As part of the Permanent Injunction, this Court ordered LYTLE to make restitution of the full amount paid to anyone who, since June 30, 2001, purchased QLaser devices from LYTLE or one of his distributors. *See* Permanent Injunction ¶19. In order to facilitate restitution to consumers, this Court ordered LYTLE to provide certain records, documents, and reports to the United States and prohibited him and all persons in active concert or participation with him, from interfering with restitution by disposing of or transferring assets or records. *See id*.

#### **COUNT ONE**

# **CONSPIRACY** (18 U.S.C. § 371)

- 14. The Grand Jury re-alleges and incorporates by reference paragraphs 1–13 of this Indictment and further charges that:
- 15. Beginning in or about January 2015, and continuing thereafter until about June 2016, in the District of South Dakota and elsewhere, Defendants,

#### ROBERT LARRY LYTLE and

#### IRINA KOSSOVSKAIA

willfully and knowingly conspired, combined, and agreed together and with individuals and entities both known and unknown to the Grand Jury, to:

- A. defraud the United States by impeding, impairing, and defeating the lawful functions of the United States Food and Drug Administration to protect the health and safety of the American public through administration of the Federal Food, Drug, and Cosmetic Act and its related regulations; and
- B. commit an offense against the United States by willfully and knowingly disobeying and resisting lawful Orders issued by the United States District Court for the District of South Dakota, in violation of Section 401(3) of Title 18 of the United States Code, to wit:
  - i. the Preliminary Injunction issued by the United States District Court for the District of South Dakota, on January 14, 2015, and entered as ECF No. 48 in the matter entitled *United States v. 2035 Inc. et al.*, Civ. No. 14-5075-JLV; and
  - ii. the Order of Permanent Injunction issued by the United States District Court for the District of South Dakota, on October 6, 2015, entered as ECF No. 138 in the matter entitled *United States v. 2035 Inc. et al.*, Civ. No. 14-5075-JLV, and as amended by the Amended Order of Permanent

Injunction, issued by the same Court in that same matter on October 13, 2015, and entered as ECF No. 139 therein.

#### Purpose of the Conspiracy

- 16. It was the purpose of the conspiracy that the Defendants and their co-conspirators, known and unknown, would continue to generate revenue through the marketing, sale, and distribution of medical devices while the distribution of such medical devices had been restrained and enjoined by the United States District Court for the District of South Dakota.
- 17. It was further the purpose of the conspiracy for the Defendants to by deceit, craft, trickery, and dishonest means, defraud the United States by obstructing, frustrating, impeding, impairing, and defeating the lawful and proper functions of the FDA to protect the American public by preventing the unlawful sale, marketing, and distribution of medical devices in interstate commerce.

#### Manner and Means of the Conspiracy

- 18. It was part of the conspiracy that notwithstanding the Court's entry of the Preliminary Injunction on or about January 14, 2015, that LYTLE, KOSSOVSKAIA, and others known and unknown to the Grand Jury continued to sell, market, and distribute QLasers, including approximately 600 QLasers that were in LYTLE's possession, custody, and control when the Court issued the Preliminary Injunction.
- 19. It was further part of the conspiracy that following the entry of the Preliminary Injunction, KOSSOVSKAIA and other co-conspirators known and unknown to the Grand Jury offered to sell QLaser devices to distributors who had obtained such devices directly from LYTLE before entry of the Preliminary Injunction.

- 20. It was further part of the conspiracy that LYTLE and others known and unknown to the Grand Jury made false and misleading statements to the FDA and the Court regarding the whereabouts and disposition of LYTLE's QLaser devices.
- 21. It was further part of the conspiracy that LYTLE created and caused others known and unknown to the Grand Jury to create false business records to make it appear that LYTLE had disposed of substantially all of his QLaser devices before entry of the Preliminary Injunction.
- 22. It was further part of the conspiracy that around the time FDA attempted to investigate LYTLE's compliance with the Preliminary Injunction in or about April 2015, LYTLE caused approximately 600 QLaser devices to be transported from their hiding place in Rapid City to KOSSOVSKAIA in New York.
- 23. It was further part of the conspiracy for KOSSOVSKAIA to hold, market, sell, and distribute QLaser devices, including approximately 600 devices she received from LYTLE in or about April 2015, in violation of the Court's Preliminary and Permanent Injunctions.
- 24. It was further part of the conspiracy for LYTLE to fraudulently transfer and conceal assets, including hundreds of thousands of dollars he received from KOSSOVSKAIA and other QLaser distributors, in order to evade the financial obligations imposed by the Court's injunctions, including restitution payments to consumers.

#### Overt Acts

25. In furtherance of the conspiracy, and to effect the purpose of the conspiracy, LYTLE, KOSSOVSKAIA and other co-conspirators known and unknown to the Grand Jury, committed and caused the following overt acts to be committed in the District of South Dakota and elsewhere:

#### **Distribution of Devices While Enjoined**

- 26. On or about January 20, 2015, after the Court's entry of the Preliminary Injunction on January 14, 2015, LYTLE instructed his business manager to create an invoice falsely dated January 2, 2015 (before the Court entered its Preliminary Injunction), that purported to show that hundreds of QLaser devices and accessories had been sold and sent to a company located in Allahabad, India, owned and operated by an unnamed co-conspirator hereinafter referred to as "JOHN DOE."
- 27. On or about January 26, 2015, LYTLE sent a letter to the Minneapolis District Office of the FDA in which he stated that he "made a decision to close the manufacturing and sale of QLasers and sold existing inventory on January 1, 2015" and that he had engaged the services of an auditor to, *inter alia*, "[v]erify that other than research QLasers there is no inventory of QLaser products."
- 28. On or about February 3, 2015, LYTLE directed his business manager to create an order form for QLaser distributors to use to buy QLaser devices notwithstanding the Preliminary Injunction. LYTLE advised distributors via electronic mail that they should use the order form to purchase "case lots" of QLaser devices being "held at a warehouse in Rapid City."
- 29. On or about February 6, 2015, LYTLE sent an email to his QLaser distributors attaching a revised order form.
- 30. On or about February 20, 2015, at LYTLE's direction, LYTLE's business manager applied for and obtained a Post Office Box at a U.S. Post Office located in Rapid City, South Dakota. On the application for the post office box, LYTLE's business manager indicated that the box would receiving mail for DOE's company, and also for two entities connected with LYTLE's QLaser business, Overshot Limited Partnership and Go-Jo Limited Partnership.

- 31. On or about March 5, 2015, LYTLE called his investment advisor in Rapid City and asked him how to manipulate his assets in order to evade their seizure in anticipation of the forthcoming permanent injunction.
- 32. On or about April 3, 2015, during an FDA inspection, LYTLE refused to comply with FDA requests to provide documents regarding the disposition of the QLaser devices and told FDA investigators he had sold all QLaser devices remaining in his inventory to his distributors and a foreign company.
- 33. On or about June 25, 2015, LYTLE shipped three QLaser devices via U.S. Mail from Rapid City, South Dakota to a consumer in Chapel Hill, North Carolina pursuant to a "Consignment Agreement."

# Surreptitious Evacuation of QLaser Inventory from South Dakota and Continued Distribution

- 34. Sometime between the FDA's inspection in April 2015, and about May 11, 2015, LYTLE caused approximately 600 QLaser devices to be delivered into the custody and control of KOSSOVSKAIA by paying a former employee to transport the devices to the Buffalo, New York, area in his personal vehicle.
- 35. On or about May 11, 2015, KOSSOVSKAIA sent an email to QLaser distributors inviting them to purchase QLaser devices from KOSSOVSKAIA "under the same conditions that were offered to you by [DOE's company]."
- 36. On or about August 11, 2015, during an FDA inspection, LYTLE provided FDA investigators with the false invoice dated January 2, 2015, that purported to show the sale of approximately 600 QLaser devices to DOE's company in India.
- 37. During the August 11, 2015, inspection, LYTLE provided FDA investigators with a letter, dated August 10, 2015, purportedly from DOE that stated that his company, located in

India, had acquired and taken possession of the QLaser devices on January 2, 2015. The letter falsely stated that none of the devices had been held or distributed within the United States after DOE's company took possession of them.

- 38. During the August 11, 2015, FDA inspection, LYTLE falsely told FDA investigators that the devices had been packaged by his business manager, who had left them in her Rapid City office to be picked up while she was out of the office on January 2, 2015.
- 39. On or about September 25, 2015, LYTLE attempted to open an off-shore account with a bank in the nation of Belize.
- 40. On or about November 4, 2015, LYTLE opened a business savings account at a bank located in Rapid City under the name "Old Cap Trust."
- 41. On or about November 5, 2015, KOSSOVSKAIA caused \$25,380 to be transferred by wire from KOSSOVOSKIA's company, Mediscen Niagara, Inc., to the Old Cap Trust bank account.
- 42. On or about May 20, 2016, KOSSOVSKAIA, through her company, HealthBoss-Mediscen, sold a QLaser device to an undercover United States Postal Inspector and shipped the device via U.S. Mail from Lewiston, New York, to Council Bluffs, Iowa.

All in violation of Section 371 of Title 18 of the United States Code.

#### **COUNT TWO**

# CRIMINAL CONTEMPT—PRELIMINARY INJUNCTION (18 U.S.C. § 401 and 18 U.S.C. § 2)

- 43. The Grand Jury re-alleges and incorporates by reference paragraphs 1–42 of this Indictment and further charges that:
- 44. Between about January 14, 2015, and about October 6, 2015, in the District of South Dakota and elsewhere, Defendants,

#### ROBERT LARRY LYTLE,

#### IRINA KOSSOVSKAIA, and

#### FREDRETTA L. EASON,

did willfully and knowingly disobey and resist, and did aid and abet each other in disobeying and resisting, a lawful writ, process, order, rule, decree, and command by a Court of the United States, namely the Preliminary Injunction issued by the United States District Court for the District of South Dakota, entered on January 14, 2015, as Electronic Case Filing ("ECF") No. 48 in the matter entitled *United States v. 2035 Inc. et al.*, Civ. No. 14-5075-JLV, in that they did directly and indirectly process, pack, label, hold, and distribute for sale and otherwise, articles of device, in violation of said Injunction.

All in violation of Sections 2 and 401(3) of Title 18 of the United States Code.

#### **COUNT THREE**

# CRIMINAL CONTEMPT—PRELIMINARY INJUNCTION (18 U.S.C. § 401)

- 45. The Grand Jury re-alleges and incorporates by reference paragraphs 1–44 of this Indictment and further charges that:
- 46. On or about April 3, 2015, within the District of South Dakota and elsewhere, Defendant,

#### ROBERT LARRY LYTLE,

did willfully and knowingly disobey and resist a lawful writ, process, order, rule, decree, and command issued by a Court of the United States, namely the Preliminary Injunction issued by the United States District Court for the District of South Dakota, entered on January 14, 2015, as ECF No. 48 in the matter entitled *United States v. 2035 Inc. et al.*, Civ. No. 14-5075-JLV, in that he refused to permit representatives of the United States Food and Drug Administration ("FDA") to take, examine, and copy records relating to medical devices and further refused to permit FDA representatives from taking measures necessary to monitor and ensure continuing compliance with the terms of the Preliminary Injunction, in violation of said Injunction.

All in violation of Sections 401(3) of Title 18 of the United States Code.

#### **COUNT FOUR**

## CRIMINAL CONTEMPT—PERMANENT INJUNCTION

(18 U.S.C. § 401 and 18 U.S.C. § 2)

- 47. The Grand Jury re-alleges and incorporates by reference paragraphs 1–46 of this Indictment and further charges that:
- 48. Beginning on or about October 6, 2015 and continuing through the date of this Indictment, Defendants,

#### ROBERT LARRY LYTLE,

#### IRINA KOSSOVSKAIA, and

#### FREDRETTA L. EASON,

did willfully and knowingly disobey and resist, and did aid and abet each other in disobeying and resisting, the lawful writ, process, order, rule, decree, and command by a Court of the United States, namely the Permanent Injunction issued on October 6, 2015, by the United States District Court for the District of South Dakota in the matter entitled *United States v. 2035 Inc. et al.*, Civ. No. 14-5075-JLV, as ECF No. 138, and as amended by the Amended Order of Permanent Injunction issued on October 13, 2015, entered by the same Court of the United States as ECF No. 139, in the same matter, by:

- A. directly and indirectly processing, packing, labeling, holding, and distributing for sale and otherwise, articles of device; and
- failing to comply with the provisions contained therein relating to restitution, as described in paragraph 13 of this Indictment,

in violation of said Injunction.

All in violation of Sections 2 and 401(3) of Title 18 of the United States Code.

#### **COUNTS FIVE THROUGH TEN**

# **MAIL FRAUD** (18 U.S.C. § 1341)

49. The Grand Jury re-alleges and incorporates by reference paragraphs 1–48 of this Indictment and further charges that:

#### Purpose of the Scheme to Defraud

- 50. It was the purpose of the scheme to defraud for LYTLE, KOSSOVSKAIA, and others known and unknown to the Grand Jury to obtain money from others through the marketing, sale, and distribution of QLaser devices by:
  - A. making false representations to consumers in an effort to convey the false impression that the QLaser device safely and effectively treated scores of human diseases and medical disorders; and
  - B. making false representations to FDA and this Court in an effort to forestall governmental action that would impede and impair the Defendants' ability to sell and distribute QLaser devices.

#### The Scheme to Defraud

- 51. It was part of the scheme to defraud that beginning at a time unknown to the Grand Jury, but no later than about 2002, LYTLE, with others known and unknown to the Grand Jury, developed a strategy to market the QLaser devices as a means for consumers to ostensibly treat more than 200 medical conditions at home, including cancer, HIV/AIDS, diseases and disorders of the eye and ear, and diabetes, by claiming that there was virtually no disorder or disease that the QLaser could not potentially improve or cure.
- 52. It was further part of the scheme to defraud that beginning at a time unknown to the Grand Jury, but no later than about September 2011, KOSSOVSKAIA participated in the scheme

to defraud, knowing of its fraudulent nature, by becoming a distributor of QLaser devices and began to sell QLaser devices to consumers.

- 53. It was further part of the scheme to defraud that LYTLE and others placed advertisements in newspapers and periodicals offering to send consumers more information about the QLaser's purported ability to "help almost every health problem ever experienced by a human being."
- 54. It was further part of the scheme to defraud that LYTLE, KOSSOVSKAIA, and others operated various internet websites that contained representations about the QLaser device's safety and effectiveness.
- 55. It was further part of the scheme to defraud for LYTLE, after receiving a notice from FDA that he was violating federal law in or about 2011, to falsely represent to FDA that he was no longer producing or marketing the QLaser devices.
- 56. It was further part of the scheme to defraud that beginning in or about 2011, LYTLE authored the *Low Level Laser Application Guide*, which LYTLE, KOSSOVSKAIA, and other QLaser distributors disseminated to consumers both together with, and independent of, QLaser devices.
- 57. It was further part of the scheme that the *Low Level Laser Application Guide* directed consumers how to use the QLaser devices to treat over 200 different diseases and disorders, such as cancer, diabetes, HIV/AIDS, hypertension, mental disturbances, and Lou Gehrig's disease (amyotrophic lateral sclerosis).
- 58. It was further part of the scheme to defraud that LYTLE, KOSSOVSKAIA, and others distributed material to consumers to create the false impression that that QLaser devices had been scientifically proven to safely and effectively treat scores of human diseases and medical disorders, including those described in the *Low Level Application Guide*.

- 59. It was further part of the scheme to defraud that LYTLE, KOSSOVSKAIA, and others distributed material to consumers falsely stating that using QLaser devices was categorically safe.
- 60. It was further part of the scheme to defraud that LYTLE, KOSSOVSKAIA, and others described LYTLE in promotional material as a retired dentist and regularly referred to him as "Doctor" or "Dr. Larry Lytle, D.D.S., Ph.D." in order to create the false impression that LYTLE was especially knowledgeable, scientifically competent, credible, and authoritative, while omitting both that his "Ph.D." was not a legitimate academic decree and also that his license to practice dentistry had been permanently revoked by South Dakota for engaging in fraud and material deception.
- 61. It was further part of the scheme that to defraud that LYTLE, KOSSOVSKAIA, and others joined together in one or more "private membership associations," which were artifices used to falsely claim to FDA and the Court that they were not selling QLasers to the public.
- 62. It was further part of the scheme to defraud for LYTLE, KOSSOVOSKIA and others to identify QLasers as being sold "for veterinary use only" in order to disguise the device's true intended use from the FDA, while representing to consumers that the device was nevertheless safe and effective for human use.
- 63. It was further part of the scheme to defraud that after the entry of the Preliminary Injunction on or about January 14, 2015, LYTLE falsely represented to the FDA and the Court that he no longer was causing QLasers to be distributed to consumers, while KOSSOVSKAIA and other distributors continued to sell QLasers to consumers and make payments to LYTLE.
- 64. It was further part of the scheme to defraud that, after entry of the Permanent Injunction, LYTLE directed a collection agency to send debt collection notices to consumers that falsely claimed that the consumers owed LYTLE and his businesses money from their QLaser

purchases, while in fact, it was the other way around—LYTLE owed consumers restitution payments pursuant to this Court's orders, which LYTLE had failed and refused to make.

### Execution of the Scheme to Defraud

65. Beginning at a time unknown to the Grand Jury, but no later than about 2002, through on or about the date of this Indictment, in the District of South Dakota and elsewhere, the Defendants,

#### ROBERT LARRY LYTLE and

#### IRINA KOSSOVSKAIA

with the intent to defraud, devised and willfully participated in, with knowledge of its fraudulent nature, the above-described scheme and artifice to defraud and obtain money by materially false and fraudulent pretenses, representations, and promises.

66. On or about the dates set forth below, in the District of South Dakota and elsewhere, for the purpose of executing and in furtherance of the above-described scheme and artifice to defraud, the Defendants,

#### ROBERT LARRY LYTLE and

#### IRINA KOSSOVSKAIA

knowingly deposited and caused to be deposited, the things and matters described below, to be sent and delivered by the United States Postal Service and private and commercial interstate carriers, according to the instructions thereon, and took and received therefrom, such things and matters as described below, each being a separate count of this Indictment:

COUNT	APPROX. DATE	FROM / TO	ITEM	CARRIER
5	October 1, 2013	Rapid City, SD / Wellington, FL	QLaser Devices	UPS

COUNT	APPROX. DATE	FROM / TO	ITEM	CARRIER
6	October 17, 2014	Rapid City, SD / Niagara Falls, NY	QLaser Devices	UPS
7	November 21, 2014	Rapid City, SD / Niagara Falls, NY	QLaser Devices	UPS
8	May 5, 2015	Billings, MT / Rapid City, SD	Check from consumer, D.C.	USPS
9	September 11, 2015	Rapid City, SD / Billings, <b>M</b> T	Change of Address Letter to consumer, D.C.	USPS
10	September 8, 2016	Rapid City, SD / Fife Lake, MI	Express Collections letter to consumer, C.C.	USPS

All in violation of Section 1341 of Title 18 of the United States Code.

#### **COUNTS ELEVEN THROUGH SIXTEEN**

## WIRE FRAUD

(18 U.S.C. § 1343)

- 67. The Grand Jury re-alleges and incorporates by reference paragraphs 1–66 of this Indictment and further charges that:
- 68. Paragraphs 50 through 64 of Counts Five through Ten of the Indictment describing the scheme to defraud are re-alleged herein and incorporated by reference.
- 69. On or about the dates set forth below, in the District of South Dakota and elsewhere, for the purpose of executing and attempting to execute the aforementioned scheme and artifice to defraud, the Defendants,

#### ROBERT LARRY LYTLE and

#### IRINA KOSSOVSKAIA

knowingly caused to be transmitted by means of wire communication in interstate commerce, the writings, signs, signals, pictures, and sounds described below for each count, each transmission constituting a separate count:

COUNT	APPROX. DATE	FROM / TO	ITEM
11	July 12, 2014	South Dakota / Montana	Email from LYTLE to QLaser customer (regarding QLaser repair)
12	February 3, 2015	South Dakota / Canada	Email from LYTLE to QLaser distributors with subject: "FDA"
13	November 5, 2015	Colorado / South Dakota	Wire transfer of \$25,380 from KOSSOVSKAIA (Mediscen Niagara) to LYTLE (Old Cap Trust)
14	December 11, 2015	Colorado / South Dakota	Wire transfer of \$28,888 from KOSSOVSKAIA (Mediscen Niagara) to LYTLE (Old Cap Trust).
15	June 6, 2016	Colorado / South Dakota	Wire transfer of \$22,732 from KOSSOVSKIA (Mediscen Niagara) to LYTLE (Old Cap Trust)

COUNT	APPROX. DATE	FROM / TO	ITEM
16	August 4, 2016	Colorado / South Dakota	Wire transfer of \$21,716 from KOSSOVSKAIA (Mediscen Niagara) to LYTLE (Old Cap Trust)

All in violation of Section 1343 of Title 18 of the United States Code.

#### **COUNT SEVENTEEN**

#### **OBSTRUCTION OF AGENCY PROCEEDING**

(18 U.S.C. § 1505)

- 70. The Grand Jury re-alleges and incorporates by reference paragraphs 1–69 of this Indictment and further charges that:
- 71. On or about April 3, 2015, the FDA conducted an agency proceeding, namely an inspection of LYTLE's business operations in Rapid City pursuant to FDA's statutory inspection authority set forth at Section 374 of Title 21, United States Code, as well as the authority granted by the Court's Preliminary Injunction.
- 72. During this proceeding, LYTLE falsely stated to FDA investigators that all QLaser devices within his companies' inventory had been sold to his distributors and a foreign company on January 1, 2015, thereby falsely misrepresenting to the FDA that he and his companies no longer had possession, custody, and control of the devices.
- 73. Further during this proceeding, LYTLE refused to provide documents and information that was lawfully requested by FDA investigators.
- 74. On or about April 3, 2015, in the District of South Dakota and elsewhere, the Defendant,

#### ROBERT LARRY LYTLE,

corruptly obstructed, impeded, and endeavored to influence, obstruct and impede the due and proper administration of the law under which a pending proceeding was being had before an agency of the United States, to wit, an inspection conducted by the United States Food and Drug Administration, by knowingly making false, fraudulent, and misleading statements, knowingly using false writings and documents, and knowingly withholding, concealing, altering, and

destroying material documents and other information that was sought in the course of said agency proceeding.

All in violation of Section 1505 of Title 18 of the United States Code.

#### **COUNT EIGHTEEN**

### **OBSTRUCTION OF AGENCY PROCEEDING**

(18 U.S.C. § 1505)

- 75. The Grand Jury re-alleges and incorporates by reference paragraphs 1–74 of this Indictment and further charges that:
- 76. Beginning on or about August 11, 2015 and continuing until about August 13, 2015, the FDA conducted an agency proceeding, namely an inspection of LYTLE's business operations in Rapid City, South Dakota, pursuant to FDA's statutory inspection authority set forth at Section 374 of Title 21 of the United States Code, as well as the authority granted by the Court's Preliminary Injunction.
- 77. During this proceeding, LYTLE provided FDA investigators with a fraudulent invoice that indicated that approximately 600 QLaser devices had been sent to DOE's company in Allahabad, India, on or about January 2, 2015.
- 78. During this proceeding, LYTLE made several false statements to FDA investigators including:
  - A. that he had neither knowledge of the operations of, nor responsibility for the various QLaser entities that he controlled;
  - B. that he had no knowledge regarding the operations of QLaser distributors such as KOSSOVSKAIA;
  - that he had consigned approximately 600 QLaser devices to DOE's company in
    India on January 2, 2015;
  - D. that he did not know who picked up the approximately 600 devices that he claimed had been consigned to DOE's company and that he did not know to where they had been transferred; and

- E. that he had not sold any QLaser devices since the entry of the Preliminary Injunction.
- 79. During this proceeding, LYTLE provided FDA investigators with a document that falsely stated that a company in Allahabad, India, had acquired and taken possession of the 600 QLaser devices on or about January 2, 2015, when in fact, these devices remained in LYTLE's custody and control, hidden at his direction in at least one home in the Rapid City area.
- 80. During this proceeding, LYTLE failed and refused to provide documents that had been lawfully requested by FDA investigators.
- 81. Beginning on or about August 11, 2015, and continuing until about August 13, 2015, in the District of South Dakota and elsewhere, the Defendant,

#### ROBERT LARRY LYTLE,

corruptly obstructed, impeded, and endeavored to influence, obstruct and impede the due and proper administration of the law under which a pending proceeding was being had before an agency of the United States, to wit, an inspection conducted by the United States Food and Drug Administration, by knowingly making false, fraudulent, and misleading statements, knowingly using false writings and documents, and knowingly withholding, concealing, altering, and destroying material documents and other information that was sought in the course of said agency proceeding.

All in violation of Section 1505 of Title 18 of the United States Code.

#### **FORFEITURE ALLEGATIONS**

- 82. The allegations contained in Paragraphs 1 through 81 of this Indictment are hereby realleged and incorporated by reference for the purpose of alleging forfeitures pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c).
- 83. Upon conviction of the offenses in violation of Sections 1341 and 1343 of Title 18, United States Code, as set forth in Counts Five through Sixteen of this Indictment, the Defendants,

#### ROBERT LARRY LYTLE and

#### IRINA KOSSOVSKAIA,

shall forfeit to the United States of America, any property, real or personal, which constitutes or is derived from proceeds traceable to the offense(s). The property to be forfeited includes, but is not limited to, the following:

- A. MONEY JUDGMENT: A sum of money equal to at least \$16,624,298, representing the amount of proceeds obtained as a result of the mail and wire fraud as charged in Counts Five through Sixteen;
- B. One (1) white 2015 Ram 1500 Longhorn pickup truck, Vehicle Identification
  Number 1C6RR7PM0FS505300;
- C. One (1) brown 2014 Ram 3500 ST diesel pickup truck, Vehicle Identification
  Number 3C63RRGL2EG165789;
- D. Two thousand, three hundred twenty-five (2,325) "Battle of the Coral Sea" ½-ounce silver bullion coins;
- E. Sixty-one (61) "Battle of the Coral Sea" 1/10-ounce gold bullion coins;

- F. The contents of a bank account held at BankWest, account number 0419, available on August 16, 2016, then containing \$33,672.41;
- G. The contents of a bank account held at BankWest, account number 4711, available on August 4, 2016, then containing \$34,441.81;
- H. The contents of a bank account held at BankWest, account number 8635, available on August 16, 2016, then containing \$28,795.26.
- I. The contents of a bank account held at First Interstate Bank, account number 0598, available on February 29, 2016, then containing \$16,474.33;
- J. The contents of a bank account held at Security First Bank, account number 0130, available on August 31, 2016, then containing \$85,468.00; and
- K. The contents of a bank account held at Pioneer Bank and Trust, account number 1877, available on July 28, 2016, then containing \$40,859.84.
- 84. If any of the property described above, as a result of any act or omission of the Defendants:
  - A. cannot be located upon the exercise of due diligence;
  - B. has been transferred or sold to, or deposited with a third party;
  - C. has been placed beyond the jurisdiction of the Court;
  - D. has been substantially diminished in value; or
  - has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Section 853(p) of Title 21 of the United States Code, as incorporated by Section 2461(c) of Title 28 of the United States Code.

Dated this 26th day of January, 2017.

### A TRUE BILL

## NAME REDACTED

**FOREPERSON** 

RANDOLPH J. SEILER UNITED STATES ATTORNEY JOYCE R. BRANDA ACTING ASSISTANT ATTORNEY GENERAL, **CIVIL DIVISION** 

Ted L. McBride

Assistant United States Attorney

<sup>6</sup>Ross S. Goldstein

Trial Attorney, Consumer Protection Branch

United States Department of Justice